SEP 2 8 2001

K010467

ADMINISTRATIVE INFORMATION

Manufacturer Name: Simplified Implant Systems, LLC
6109 N. Lafayette Avenue
Fresno, CA 93711

Official Contact: Theodore S. Falk, D.D.S.
Telephone (559) 229-3556
FAX (559) 227-1668

DEVICE NAME

Classification Name: Endosseous dental implant

Trade/Proprietary Name: Universal Dental Coping (UDC)

Common Name: Dental Implant

ESTABLISHMENT REGISTRATION NUMBER

Simplified Implant Systems, L.L.C. is registered with FDA under Establishment Registration Number 2954291 and Owner/Operator Number 9033334.

DEVICE CLASSIFICATION

Endosseous dental implants have been classified by FDA as Class III devices under a final order published in the Federal Register of August 12, 1987, as shown in 21 CFR 872.3640. Abutments to such implants and other components of dental implant systems that remain in contact with tissues for more than one hour are considered by FDA to be Class III devices inasmuch as they are used as accessories to or are used with endosseous dental implants. The device is reviewed by the Dental Products Panel and the Product Code for the device is DZE.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514.

INTENDED USE

The Simplified Implant Systems Universal Dental Coping (UDC) is intended for use as a base for a temporary restoration, as an impression coping and as a laboratory casting

pattern used in the fabrication of a permanent single-tooth or multiple-tooth restoration to be supported by dental implants.

DEVICE DESCRIPTION

Design Characteristics

The Simplified Implant Systems UDC consists of a series of components that are designed to be used for dental implant restorative techniques. Of the components included in the UDC, one type is intended for use as a base for a temporary restoration and is, therefore, a Class III device covered under the endosseous implant classification. The others are laboratory components that do not contact tissues or do not remain in contact with tissues for more than one hour. They are, therefore, included in the October 10, 2000 reclassification of accessories to dental implants (FR 65 60098). Such components are discussed herein for reference only and are not subjects of this Premarket Notification.

The UDC fits over the conical abutment after the abutment is placed. The UDC serves to prevent the impingement of periodontal tissue on the collar of the implant, while providing a base for fabrication of an acrylic or composite temporary restoration. Tissue impingement on the collar of the implant would make subsequent treatment difficult without removal or excessive retraction of tissue. The UDC includes radial projections that facilitate the retention of added acrylic or composite materials that are used to fabricate the temporary restoration. The UDC becomes part of the temporary restoration and facilitates the fit of the restoration to the implant and abutment by means of its precise inner surface. Though allowance is made for cement, cement is not needed to retain the UDC/temporary restoration on the implant/abutment, due to the tight "snap" fit of the UDC to the implant margin. The UDC is not intended to be screw-retained.

The UDC also functions as an impression coping and is used in conjunction with a plastic die analog as a "burn-out" pattern in fabricating the permanent restoration. These applications of the UDC and die analog are exempt from premarket notification.

Material Composition

All Simplified Implant Systems UDC components are fabricated from a thermoplastic polymer by injection molding.

EQUIVALENCE TO MARKETED PRODUCT

Simplified Implant Systems, L.L.C. submits the following information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Universal Dental Coping is substantially equivalent in indications and design principles to components or uses of the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: the Brånemark CeraOne Temporary Cap (K910611) and Temporary Cylinder to Fixture, the Sulzer Calcitek Spline Dental Implant System Temporary Abutment (K982305), Lifecore Temporary Sleeves for Conical Abutments and Steri-Oss Conical Abutment Temporary Copings.

The Simplified Implant Systems UDC also is equivalent in function to the technique of fabricating a provisional acrylic restoration .

Intended Uses

The indications for use for the Simplified Implant Systems UDC and the predicate devices are substantially the same. All are intended for fabrication of temporary restorations supported by dental implants.

Design and Materials

For the purposes of FDA's regulation of medical devices, the design and functional characteristics of the Simplified Implant Systems UDC and the predicate devices are the same. They all function as a base for the fabrication of a temporary prosthetic restoration, either with or without retention screws. The closest predicate to the UDC is the Brånemark CeraOne Temporary Cap. It is intended to fit over the CeraOne abutment and includes radial projections for retention of acrylic used for fabrication of a temporary prosthesis. In the fabrication of a screw-retained temporary restoration, such as with the use of the predicate devices from Sulzer Calcitek, Lifecore and Steri-Oss, titanium is used in order to provide sufficient strength at the seating surface of the screw. The Brånemark Temporary Cylinder to Fixture, though screw-retained, is made from a polymeric material, presumably to facilitate adhesion of acrylic or composite resin used for fabrication of a temporary prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

Mr. Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K010467
Trade/Device Name: Universal Dental Coping (UDC)
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: February 13, 2001
Received: February 16, 2001

Dear Mr. Larson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Name: Simplified Implant Systems Universal Dental Coping (UDC)

Indications for Use:

Intended for use as a base for a temporary restoration, as an impression coping and as a laboratory casting pattern used in the fabrication of a permanent single-tooth or multiple-tooth restoration to be supported by dental implants.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010467